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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,356	08/21/2001	Dale E. Koop	CTC-401	7685

7590 01/03/2005

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EXAMINER	
FARAH, AHMED M	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,356	KOOP, DALE E.	
	Examiner	Art Unit	
	Ahmed M Farah	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *27 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The written description fails to clearly teach the newly recited step of 'stimulating collagenesis without coagulation of collagen.'

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 6, and 8-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Purchio et al. U.S. Patent 5,599,788.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

However, Purchio et al. disclose a method of producing recombinant transforming growth factor -induced H3 protein and its use to accelerate wound healing (see Col. 4, line 65 to Col. 5, line 9). They further teach that H3 protein may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency (Col. 4, lines 58--60).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Purchio et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

As to claim 6 of the instant application, claim 3 of O'Donnell, Jr. teaches the claimed limitation.

3. Claim 7 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Tankovich et al. U.S. Patent 5,817,089 in view of Purchio et al. ('788).

Tankovich et al. disclose phototherapy treatment methods for the reduction and removal of unwanted hair and the mitigation of skin conditions such as acne and seborrhea. However, they do not apply wound healing promoter composition to the skin to enhance the healing process.

Purchio et al., described above, teach the use of a wound healing protein, which may be combined with conventional chemotherapy and radiation treatment to increase the over all treatment efficiency. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify the invention of Tankovich et al. with Purchio et al. to apply a wound healing protein to the skin being treated so as to enhance the wound healing process and improve the over all treatment efficiency.

4. Claims 1-3, 6 and 8-11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over O'Donnell, Jr. U.S. Patent 6,106,514 in view of Hale et al. U.S. Patent 5,607691.

O'Donnell, Jr. discloses apparatus and method for treating subsurface layer of skin, the method comprising the steps of:

applying anti-inflammatory, anti-oxidant (wound healing) pharmaceutical agent to the skin (Col. 3, lines 21-26); and

irradiating the skin with laser energy sufficient to cause stimulation of collagen remodeling for the purpose of effecting the tightening of the skin and reducing wrinkles without significantly altering the epidermis (see claims 1-3).

As to claim 3, O'Donnell, Jr. applies mechanical energy to the skin tissue (Col. 6, lines 6-10).

As to claim 8, his treatment reduces wrinkles. Therefore, since wrinkles result from photodamaged and/or aging skin, he provides the claimed method step.

Although O'Donnell, Jr., described above, discloses pharmaceutical agent to enhance the treatment, he does not teach the use of growth factor such as H3 protein to promote the healing process.

Hale et al. disclose a method for treating the skin of a patient, the method comprising the steps of: delivering to the skin a pharmaceutical agent such as H3 protein (Col. 26, lines 22-39; Col. 45, lines 35-41; and Col. 51, lines 17-40); and applying EM energy to the skin being treated (Col. 50, lines 27-39).

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify O'Donnell, Jr. and apply a growth factor such as H3 protein to the skin as taught by Hale et al. in order to accelerate the wound healing and to enhance the over all treatment efficiency.

Response to Arguments

5. Applicant's arguments filed on September 27, 2004, have been fully considered but they are not persuasive. The applicant's argument is mainly based on the newly recited term in the claims that the claimed invention is directed to treatment methods for "stimulates collagenesis without coagulation of collagen." However, the applicant's

written description fails to clearly teach this recitation. Furthermore, O'Dannell ('514) clearly teaches that his invention stimulates increase of new collagen (see the abstract).

The applicant further argues that there is a difference between the treatment energy disclosed in the present application and the one used by O'Dannell ('514). However, the applicant's claims fail to recite the parameters of the treatment energy.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,
Primary Examiner, AU 3739

December 27, 2004.